

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 19453: Propanoic acid, 2-hydroxy, (2S)-, compounds with hydrolyzed bisphenol A-epichlorohydrin polymer-diethanolamine-*N*1-(dialkylalkylidene)-*N*2-[2-[(dialkylalkylidene)amino]ethyl]-1,2-ethanediamine reaction products (Confidential Accession No. 19317-5)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified polymer is propanoic acid, 2-hydroxy, (2S)-, compounds with hydrolyzed bisphenol A-epichlorohydrin polymer-diethanolamine-*N*1-(dialkylalkylidene)-*N*2-[2-[(dialkylalkylidene)amino]ethyl]-1,2-ethanediamine reaction products (Confidential Accession No. 19317-5). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains cationic amine groups.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in automotive coatings. Potential uses may include use in consumer coating products.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil and sediment. The substance is expected to be persistent in these compartments because it does not contain any functional groups that are susceptible to hydrolysis or biodegradation. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish (median lethal concentration (LC₅₀) 1-100 mg/L), low to moderate acute toxicity in aquatic invertebrates (median effective concentration >1 mg/L), and moderate chronic toxicity in algae (no-observed-effect concentration 0.1-10 mg/L) under environmental conditions mitigated by humic acid. Using the LC₅₀ from the most sensitive organism (fish) and by applying an assessment factor of 100 to account for

acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L, which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from cleaning of transportation vessels and use in automotive coatings, with release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. For potential activities such as manufacturing and formulation, environmental exposure is expected to be similar to that of the notified use.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used in automotive coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at negligible levels as any residual substance in water following waste water treatment will not lead to elevated environmental concentrations because it will be strongly adsorbed to organic materials in the water and to sediment.

Potential uses of the substance include consumer paints and coatings, where direct exposure of the general population is expected to be mainly by contact with the skin at very low levels. Systemic exposure will be limited by the substance's high molecular weight and cationic nature which will limit its ability to cross biological membranes, and the slow rate of diffusion of the substance through paints and coatings. The substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Other potential consumer uses of the substance include spray coatings, where direct exposure by inhalation is expected to be at low levels given that the substance is not expected to enter the vapor phase. Indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for exposure and the absence of structural features associated with adverse human health effects, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.